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Office of Pesticide Programs
Environmental Protection Agency, (28221T)
1200 Pennsylvania Ave., NW
Washington, DC 20460-0001

**Re: Human Health Draft Risk Assessment for Registration Review. Docket No: EPA-HQ-OPP-2009-0317**

Dear Sir/Madam,

Please accept these comments on behalf of Beyond Pesticides for the draft human health risk assessment for the insecticide malathion. The U.S. Environmental Protection Agency (EPA) has completed a comprehensive review of the chemical and its uses, but there are still some shortcomings in the assessment we would like to bring to the attention of the agency. Malathion is an organophosphate (OP) insecticide widely used agriculture on numerous crops, and as an adulticide for mosquito control. Like other chemicals in its class, malathion is a cholinesterase inhibitor resulting in neurological impairments.

The scientific database is clear on the neurological risks associated with exposure to malathion and other organophosphates. Malathion's use as a mosquito adulticide draws concern regarding its impact on communities and non-target organisms. Broadcast aerial and ground applications of malathion for mosquito control exposes the public, including vulnerable sub-populations like children and those with weakened nervous and immune systems, to a neurotoxic agent that has the potential to cause lasting neurological harms, despite the *Food Quality Protection Act* (FQPA) safety factors.

EPA's assessment of residential and occupational exposures to malathion shows that there are risks of concern that cannot be ignored, and given the legacy of OP uses, must finally be phased out. In light of this, EPA must carry out its statutory responsibility under the *Federal Insecticide Fungicide and Rodenticide Act* (FIFRA) to protect human and environmental health

from the impacts of malathion and other OPs due to pervasive exposures and unreasonable neurotoxic impacts on human health.[1,2,3,4]

Residential Risks from Malathion's Mosquito Uses

Given the current concerns regarding mosquito-borne diseases, especially the Zika virus, it is critical that chemical control options be thoroughly reviewed and vetted for their safety to human and environmental health. OPs like malathion should not be an option for mosquito control due to their high neurotoxic potential. Both large-scale and on-site residential applications pose risks to the general public.

According to EPA, risks for dermal and inhalation exposures were identified, especially those associated with adulticide applications. Specifically, the agency states, "All dermal exposure and risk estimates for adults and children (1 to <2 years old and 6 to 11 years old) were of concern… for the aerial mosquitocide applications, residential garden uses, and pick-your-own scenarios…Inhalation exposure from the aerial mosquitocide applications were also of concern….for adults and children." Additionally, spray drift as a result of aerial applications results in major risk concerns.[5] For aerial and ground-based applications EPA found that there are numerous residential exposure pathways of concern "for all post-application scenarios." These include dermal, inhalation, hand-to-mouth and object-to-mouth scenarios. In light of these risk concerns from aerial and ground mosquito adulticiding, we urge the agency to revoke malathion mosquito uses.

Other mosquito use scenarios for the residential assessment include, hose-end sprayer, manually pressurized handwand, backpack, and outdoor fogger/misting system. These application methods release malathion residues into the air and result in direct acute inhalation and dermal exposures, as well as post-application dermal and inhalation exposures. Given that all dermal risk estimates are of concern, as well as inhalation exposures for manually pressurized handwand applications, hose-end sprayer applications, backpack application, and for misting/fogger applications, we recommend that these residential mosquito applications be revoked.

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[1] Rauh VA, Perera FP, Horton MK, et al. 2012. Brain anomalies in children exposed prenatally to a common organophosphate pesticide. *Proc Natl Acad Sci U S A*. 109(20):7871-6.

[2] Morgan, M. K., Wilson, N. K., and Chuang, J. C. 2014. Exposures of 129 Preschool Children to Organochlorines, Organophosphates, Pyrethroids, and Acid Herbicides at Their Homes and Daycares in North Carolina. *International Journal of Environmental Research and Public Health*, *11*(4), 3743–3764. doi:10.3390/ijerph110403743.

[3] Chen, XP, Chen, WF and Wang DW. 2014. Prenatal Organophosphates Exposure Alternates the Cleavage Plane Orientation of Apical Neural Progenitor in Developing Neocortex. PLoS One. 9(4): e95343.

[4] Androutsopoulos VP, Hernandez AF, Liesivuori J, Tsatsakis AM. 2013. A mechanistic overview of health associated effects of low levels of organochlorine and organophosphorous pesticides. Toxicology 307:89-94.

[5] USEPA. 2016. Malathion: Human Health Draft Risks Assessment for Registration Review. Office of Chemical Safety and Pollution Prevention. Washington DC.

Malathion Drift Risk Estimates

Post-application drift leads to indirect exposures that must also be taken into account. EPA conducted a spray drift assessment and found, not surprisingly, that "the major spray drift risk concern is from aerial applications." While spray drift leads to indirect exposures, direct exposures, especially for aerial applications, do occur. EPA states, "Quantitatively, incorporating spray drift into risk assessment is based on a premise of compliant applications which, by definition, should not result in direct exposures to individuals because of existing label language and other regulatory requirements intended to prevent them." EPA believes indirect drift exposures occur through "contact with impacted areas," like residues on turf.[6]

However, EPA should be aware that drift is inevitable with pesticide application regardless of compliance or mitigation measures, which have not been proven successful in preventing drift. Additionally, aerial applications potentially leads to residues drifting significant distances leading to inhalation and dermal exposures not sufficiently accounted for. EPA's approach to evaluate risks posed by malathion drift focuses on deposited residues on turf. While this is one exposure pathway as a consequence of drift, other pathways are possible and should be considered, including indoor inhalation and dermal exposures, exposures to residues on hard surfaces and waters (eg swimming pools). We urge EPA is expand its assessment for spray drift to incorporate a comprehensive assessment of all potential risks.

Occupational Exposures

The occupational assessment identified handler and post-application risks, including mixing/loading, handheld, and airblast applications. However, certain assessments –post application inhalation exposure assessment, were not carried out. EPA states that current agency practices/proceedures do not allow for this assessment to be completed, and that should new policies be put into place, the agency may revisit this issue. This means that farmworkers and other pesticide handlers remain at risk from unevaluated malathion exposures. This is unacceptable. If EPA policies do not allow for the evaluation of these risks, the chemical should not be allowed to be used in ways that result in occupational inhalation exposures.

Unrealistic Labels Lead to Unintended Exposures

According to EPA, registered product labels for some of these products require the use of specific clothing (long sleeves, long pants) and the use of personal protective equipment (PPEs), including those registered for residential uses. EPA states, "Some of the registered malathion product labels with residential use sites (e.g., home ornamental and vegetable gardens as well as spot and perimeter outdoor uses for insect and mosquito control) require that handlers wear specific clothing (e.g., long sleeve shirt/long pants) and/or use personal protective equipment (PPE). There, HED has *made the assumption that these products are not*

[6] Ibid.

*for homeowner use, and has not conducted a quantitative residential handler assessment [emphasis added]*." It is curious that on a general use product label (discussed below) that EPA approved that it is NOT made clear whether homeowners or professionally trained applicators will be applying the product. It is also alarming that EPA will then "assume" that homeowners will not be applying the product, and therefore not conduct a residential assessment for these uses.

These products are either mislabeled and/or misbranded and in violation of the FIFRA, and should be removed from the market. Further, EPA cannot assume that homeowners will not be applying or become exposed to these malathion products if there is no indication on the label that it is for professional or restricted use only. Upon further review of these products, the label inconsistencies become evident and even more concerning, since EPA is basing assessment of these products on use assumptions.

Common formulations consist of around 50 percent malathion as the sole active ingredient. But while use and application methods are similar, varying precautionary statements are recommended. For instance, Acme Malathion 50% Spray (EPA Reg No: 33955-394) -listed by EPA as one of the products that calls for PPEs and therefore *not* for homeowner use- has similar formulation (petroleum-based solvents) and application method to Hi-Yield 55% Malathion Spray (EPA Reg No: 7401-10) which has no PPE recommendation, and thus will be assumed for homeowner use. Ortho Malathion Insect Spray (EPA Reg No: 239-739) recommends PPEs but is clearly marketed to homeowners.[7] All three products require users to dilute the product for spray applications (including tank spraying) and a quick internet search finds they are available for purchase online with no apparent restrictions. However, despite similarities in formulation, use pattern, and application methods, these products will be assessed differently due to EPA's assumption that homeowners will not be applying products with PPEs statements. This is unacceptable and we recommend EPA conduct comprehensive and complete residential handler assessments for all malathion products.

In addition to residential uses, EPA is recommending label language for adulticide/public health uses: "Use in agricultural areas must be in a manner as to ensure that residues do not exceed the established federal tolerance for the active ingredient in or on raw agricultural commodities resulting from use for wide area pest control."[8]

Given multiple repeat aerial and ground applications of adulticides, especially in mosquito prone areas, we question which stakeholder will be responsible for complying with this language/ tolerance stipulation. The farmer, who has no control over aerial residues depositing on his/her crops yet must meet federal tolerance standards? The contracted applicator, or the local vector control authority/state department? Clarification is needed before such a

[7] https://www.amazon.com/Ortho-Malathion-Concentrate-Insect-16-Ounce/dp/B00B1OVVUC.

[8] USEPA. 2016. Malathion: Human Health Draft Risks Assessment for Registration Review. Office of Chemical Safety and Pollution Prevention. Washington DC.

statement can be approved to avoid undue burdens on farmers, especially organic farmers who are typically disproportionately and economically impacted by pesticide drift.

Malathion Health Risks

In its assessment, EPA details a comprehensive overview of the mechanism of neurotoxicity for malathion/OPs in the nervous system. Malathion is classified as "suggestive evidence of carcinogenicity but not sufficient to assess human carcinogenic potential" by all routes of exposure. EPA notes that, at this time, "Review of the available epidemiologic evidence considered independently is not sufficient to support a conclusion that additional hazard identification and exposure-response modeling [is] needed within the risk assessment." However, the International Agency for Research on Cancer (IARC) assessed the carcinogenicity of malathion in 2015 and classified it as "probably carcinogenic" to humans (Group 2A).[9] This was based on limited evidence from exposure studies for non-Hodgkin lymphoma and prostate cancer and rodent studies in which malathion caused tumor development.

Malathion is rapidly absorbed through the gastrointestinal tract, skin, and lungs and exhibits low acute toxicity through these routes.[10] One study finds malathion has genotoxic potential.[11] Another reports that malathion exposures induce cytotoxic and genotoxic effects in HepG(2) cells.[12] The agency notes that it will follow the science around malathion's associations with other chronic disease.

In the 2006 OP cumulative assessment, EPA stated that malathion uses (agriculture, residential, public health) were not significant contributors to the cumulative risk assessment and, as a result, refinement for brain cholinesterase inhibition from the metabolite, malaoxon, was not necessary. However, malaoxon is active in acetylcholinesterase inhibition and more potent than malathion. Based on this, further consideration of malaoxon is warranted. In this assessment, EPA evaluated the ratio of toxicity between malathion and malaoxon and found that malaoxon is 22 times more toxic than malathion.[13] Given the available toxicological evidence, exposures to malathion and its metabolite malaoxon should be significantly restricted from agriculture, residential and public health uses.

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[9] Fritschi, L., McLaughlin, J., Sergi, C. M., Calaf, G. M., Le Curieux, F., Forastiere, F., ... & Martin, M. T. (2015) Carcinogenicity of tetrachlorvinphos, parathion, malathion, diazinon, and glyphosate. *Red*, *114*.

[10] U.S. EPA. 2009. Reregistration Eligibility Decision (RED) for Malathion. Office of Pesticides and Toxic Substances. Washington, DC.

[11] Moore PD, Patlolla AK, Tchounwou PB. 2011. Cytogenetic evaluation of malathion-induced toxicity in Sprague-Dawley rats. *Mutat Res.*;725(1-2):78-82.

[12] Moore PD, Yedjou CG, Tchounwou PB. 2010. Malathion-induced oxidative stress, cytotoxicity, and genotoxicity in human liver carcinoma (HepG2) cells. *Environ Toxicol*. 25(3):221-6.

[13] USEPA. 2016. Malathion: Human Health Draft Risks Assessment for Registration Review. Office of Chemical Safety and Pollution Prevention. Washington DC.

## Organophosphate Class Should Be Phased Out

Organophosphate insecticides, like malathion, are neurotoxic cholinesterase inhibitors that cause the buildup of acetylcholine (AChE), leading to uncontrolled rapid twitching of some muscles, paralyzed breathing, convulsions, and, in extreme cases, death. They have also been linked to developmental delays, impaired cognitive development, and a host of learning/behavioral problems in young children.[14,15] It is paramount that the public's health is safeguarded from unnecessary exposures to such neurotoxins. Despite numerous organophosphate poisonings of farmworkers, homeowners, and children, EPA has allowed the continued registration of many of these products. In some cases, such as chlorpyrifos and diazinon, household uses of the products have been cancelled because of the extreme health risks to children, but agricultural, golf course, and "public health" (mosquito control) uses remain on the market. EPA's 2006 cumulative risk assessment document considered the cholinesterase inhibition mechanism for neurotoxic effects of OPs.[16] However studies show that there are other mechanisms at work, resulting in nervous system toxicity. Studies show that at very low levels OPs can induce additional neurotoxic effects at concentrations below those for inhibition of AChE. These studies find that OP-mediated toxicity is a combination of various enzyme-inhibitory, metabolic, and transcriptional events acting at the cellular and molecular level.[17,18,19] With OPs' common mechanism of toxicity and aggregate exposures from food, water and pesticide drift from applications, coupled with their low-level potency, the agency must act with urgency to formally revoke all registrations and uses of this class of pesticide.

## Conclusion

EPA's draft human health assessment of malathion has reinforced the calls from Beyond Pesticides and allies for the revocation of this and other OP uses. This class of chemicals is highly neurotoxic and continued use puts the public at risk. EPA has identified several risks of concern related to malathion use that cannot be ignored or successfully mitigated. Dermal and inhalation exposures continue to pose the highest risk from residential and occupational uses. Spray drift, which is inevitable given the current allowable uses of malathion, also raises concern. We remain especially concerned about continued allowable uses for wide-area mosquito control (aerial and ground applications) in light of current mosquito-control action in

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[14] Rauh VA, Perera FP, Horton MK, et al. 2012. Brain anomalies in children exposed prenatally to a common organophosphate pesticide. *Proc Natl Acad Sci U S A*. 109(20):7871-6.

[15] Lovasi, GS, et al. 2011. Chlorpyrifos Exposure and Urban Residential Environment Characteristics as Determinants of Early Childhood Neurodevelopment. *Am J Public Health;*101(1):63-70.

[16] USEPA. 2006. Organophosphorus Cumulative Risk Assessment. Office of Pesticide Programs. Washington DC

[17] Androutsopoulos VP, Hernandez AF, Liesivuori J, Tsatsakis AM. 2013. A mechanistic overview of health associated effects of low levels of organochlorine and organophosphorous pesticides. Toxicology 307:89-94.

[18] Lee I, Eriksson P, Fredriksson A, et al. 2015. Developmental neurotoxic effects of two pesticides: Behavior and biomolecular studies on chlorpyrifos and carbaryl. Toxicol Appl Pharmacol. 288(3):429-38

[19] Meijer M, Hamers T, Westerink RH. 2014. Acute disturbance of calcium homeostasis in PC12 cells as a novel mechanism of action for (sub)micromolar concentrations of organophosphate insecticides. Neurotoxicology. 43:110-6

several states and U.S. territories. We object to the use of neurotoxic agents to combat mosquito populations, given the safer, more efficacious alternatives. We urge EPA to move forward with the cancellation of malathion uses.

Respectfully,

Nichelle Harriott
Science and Regulatory Director